Maryland General Assembly
Department of Legislative Services

Proposed Regulations
Department of Health and Mental Hygiene

(DLS Control No. 15-078)

Overview and Legal and Fiscal Impact

The regulations set forth the process for qualifying patients to obtain medical cannabis in the State, including: (1) the establishment of standards for individuals to register as a qualifying patient to obtain medical cannabis; (2) the requirements for licensed physicians in the State to be registered to recommend medical cannabis; (3) the requirements for growers, processors, and dispensaries to be licensed by the Natalie M. LaPrade Medical Cannabis Commission and for grower agents, processor agents, and dispensary agents to be registered by the commission; (4) the establishment of requirements for caregivers; (5) the establishment of certain application processes; (6) the establishment of certain security standards; (7) the procedure to be followed by the commission when conducting certain inspections; (8) the establishment of labeling and packaging standards; (9) the authority of the commission to take certain disciplinary action; (10) the establishment of a complaint procedure; and (11) the establishment of certain fees to fund the operations of the commission.

The regulations present no legal issue of concern.

The regulations have no material fiscal impact on State or local government expenditures beyond the expenditures assumed for the same period in the fiscal and policy notes for Chapters 240 and 256 of 2014 and Chapter 251 of 2015. This estimate accounts for delayed start-up costs from fiscal 2015 to fiscal 2016. While special fund fee revenues were anticipated as early as fiscal 2016, the amount could not previously be estimated. However, under these regulations and with aggressive implementation and the assumptions outlined below, as much as $4.5 million in special fund fee revenues could be realized in fiscal 2016 (with approximately $4.2 million in fiscal 2017 and $4.4 million in 2018); some portion of this revenue estimate could also be delayed. General fund revenues may increase minimally due to the imposition of fines.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Natalie M. LaPrade Medical Cannabis Commission: Definitions: COMAR 10.62.01.01 and .02
General Regulations: COMAR 10.62.02.01-.04
Certifying Physicians: COMAR 10.62.03.01-.03
Patient and Caregiver Registry: COMAR 10.62.04.01-.06
Written Certifications: COMAR 10.62.05.01 and .02
Patient and Caregiver Identification Cards: COMAR 10.62.06.01-.07
New Condition Approval Process: COMAR 10.62.07.01-.06
Medical Cannabis Grower License: COMAR 10.62.08.01-.11

Medical Cannabis Grower Agent: COMAR 10.62.09.01-.09
Medical Cannabis Grower Premises: COMAR 10.62.10.01-.08
Medical Cannabis Growing Controls: COMAR 10.62.11.01-.04
Inventory Control by Grower: COMAR 10.62.12.01-.08
Medical Cannabis Shipment Packaging: COMAR 10.62.13.01 and .02
Licensed Grower Dispensary Facility: COMAR 10.62.14.01 and .02
Medical Cannabis Grower Quality Control: COMAR 10.62.15.01-.08
Licensed Independent Testing Laboratory Registration: COMAR 10.62.16.01-.05
Complaints, Adverse Events, and Recall: COMAR 10.62.17.01-.04
Shipment of Products Between Licensees: COMAR 10.62.18.01-.06
Medical Cannabis Processor License: COMAR 10.62.19.01-.09
Medical Cannabis Processor Agent: COMAR 10.62.20.01-.09
Medical Cannabis Processor Premises: COMAR 10.62.21.01-.07
Medical Cannabis Processor Operations: COMAR 10.62.22.01-.06
Medical Cannabis Concentrates and Medical Cannabis-Infused Products: COMAR 10.62.23.01-.07
Medical Cannabis Finished Products Packaging: COMAR 10.62.24.01
Medical Cannabis Dispensary License: COMAR 10.62.25.01-.10
Dispensary Agent: COMAR 10.62.26.01-.09
Licensed Dispensary Premises: COMAR 10.62.27.01-.09
Licensed Dispensary Operations: COMAR 10.62.28.01-.05
Licensed Dispensary Packaging and Labeling for Distribution: COMAR 10.62.29.01 and .02
Dispensing Medical Cannabis: COMAR 10.62.30.01-.09
Licensed Dispensary Clinical Director: COMAR 10.62.31.01
Records: COMAR 10.62.32.01-.03
Inspection: COMAR 10.62.33.01-.08
Discipline and Enforcement: COMAR 10.62.34.01-.04
Fee Schedule: COMAR 10.62.35.01

Legal Analysis

Background

Chapter 403 of 2013 authorized the investigational use of marijuana for medical purposes through research programs operated by academic medical centers in the State. The Act also established the Natalie M. LaPrade Medical Marijuana Commission, as an independent commission within the Department of Health and Mental Hygiene. The commission initially was established to (1) develop requests for applications for academic medical centers to operate programs in the State; (2) approve or deny initial and renewal program applications; and (3) monitor and oversee programs approved for operation.

Due to a lack of interest among academic medical centers to participate in the program and pressure from patient advocates to make medical marijuana available beyond only those patients participating in a research study, legislation was introduced in 2014 to expand the medical marijuana program. Chapters 240 and 256 of 2014 expanded the State's medical marijuana program to allow qualifying patients to obtain medical marijuana from persons other

than academic medical centers. Specifically, the Acts allowed a qualifying patient who had been provided with a written certification from a certifying physician in accordance with a *bona fide* physician-patient relationship to obtain medical marijuana from a grower or dispensary licensed by the commission. The Acts also required the commission to adopt certain regulations to implement the program on or before September 15, 2014.

The commission met monthly following enactment of Chapters 240 and 256 and created subcommittees to assist in the drafting of regulations. The commission published proposed regulations in the January 23, 2015 issue of the *Maryland Register* that implemented Chapters 240 and 256. On March 9, 2015, the AELR committee placed the regulations on hold, as legislation that would significantly alter the commission's duties was being considered by the General Assembly during the 2015 legislative session.

Chapter 251 of 2015 significantly revised the duties of the commission by: renaming the commission to be the Natalie M. LaPrade Medical Cannabis Commission; repealing the commission's authority to approve academic medical centers to operate programs; altering the membership, authority, and duties of the commission; authorizing a certifying physician to include in a written statement that a 30-day supply of medical cannabis may be inadequate to meet the medical needs of the qualifying patient; authorizing growers to grow and process medical cannabis on the same premises; authorizing the commission to license processors and processor agents, to register independent testing laboratories, and to inspect dispensaries, processors, and testing laboratories; and authorizing a person to be licensed concurrently as a grower, dispensary, and processor. The regulations implement the provisions of law relating to the Natalie M. LaPrade Medical Cannabis Commission as amended by Chapter 251 of 2015.

Summary of Regulations

Chapter 10.62.01 provides definitions for the subtitle. Definitions for "caregiver", "certifying physician", "commission", "dispensary agent", "Fund", "independent testing laboratory", "licensed dispensary", "licensed grower", "licensed processor", "qualifying patient", and "written certification" generally track statutory definitions included in Title 13, Subtitle 33 of the Health – General Article. The regulations also provide additional terms, the definitions of which are not derived from statute.

Chapter 10.62.02 provides general regulations concerning the commission. The regulations specify conditions for acceptance of private donations to the Natalie M. LaPrade Medical Cannabis Commission Fund. The regulations also require all commission activities to be conducted in compliance with HIPAA regulations. The regulations require the commission to broadly publicize that the commission will be seeking the submission of applications: (1) for licenses to grow, process, and dispense medical cannabis; and (2) to register patients, physicians, and independent testing laboratories from all interested persons throughout the State.

Chapter 10.62.03 concerns certifying physicians. The regulations require physician applications for certification by the commission to include: (1) an attestation that the physician has an active Maryland license to practice medicine that is in good standing, that the physician is registered to prescribe controlled substances by the State, and that a standard patient evaluation will be completed; (2) the medical conditions for which the physician may issue written certifications and the physician's other inclusion criteria; and (3) the reasons the physician may

deny issuing a written certification. The regulations provide that an application is deemed approved unless the commission notifies the applicant that the application has been denied.

A certifying physician may not receive certain compensation from a licensed grower, licensed processor, or licensed dispensary unless the certifying physician submits a certain application that discloses certain information to the commission for approval of the compensation. The commission may deny the application under certain circumstances, and a physician is entitled to a hearing to review the denial. The regulations also provide for the renewal of a certifying physician's registration, which is valid for two years.

Chapter 10.62.04 requires the commission to establish a patient and caregiver registry. An individual seeking to become a qualifying patient must provide certain information to the commission, and the commission is required to assign a unique patient identifier to each individual who registers. The regulations also set forth the requirements for a caregiver to register with the commission via the commission's website. The regulations authorize a qualifying patient to terminate or add a caregiver. Finally, the regulations require the commission to provide access to the registry to a Maryland law enforcement agency on a real-time basis only for just cause to verify that a patient or caregiver is registered.

Chapter 10.62.05 sets forth the requirements for written certifications, the procedures to be followed by a certifying physician to transmit a written certification to the commission, and the information to be included in a written certification. A certifying physician may terminate a written certification under certain circumstances, and the regulations authorize the renewal of a written certification not less than 30 days after being issued under certain circumstances.

Chapter 10.62.06 concerns patient and caregiver identification cards, including the information to be provided to the commission when applying for a card. The regulations require a cardholder to report a lost, destroyed, or stolen card within 72 hours of becoming aware of the loss, destruction, or theft. In addition, the regulations set forth requirements related to change of name or address, circumstances requiring the return of the card, renewal of the card, and misuse of the card.

Chapter 10.62.07 concerns the new condition approval process and requires an individual who wishes to suggest a medical condition, medical treatment, or disease for commission consideration to submit a certain petition to the commission. At least once a year if needed, the commission must conduct a public hearing to evaluate any petition. The commission may deny a petition without submitting it for public comment under certain circumstances. Following the hearing, the commission must consider public comments and additional available information or expertise and may conclude that physicians will be encouraged to apply to register with the commission to treat the condition, treatment, or disease if a certain determination is made by the commission.

Chapter 10.62.08 sets forth the requirements to obtain a medical cannabis grower license. The regulations address applications for medical cannabis grower licenses and require each individual identified in an application for a grower license to consent for the commission and persons authorized by the commission to verify application information and conduct background investigations. The regulations establish procedures for application review, including grounds for denial or suspension. Applicants are ranked according to weighted criteria developed by the commission, and the commission may take into account the geographic location of the growing operation to ensure there is geographic diversity in the award of licenses. The regulations reflect

statutory limitations on the number of grower licenses the commission may approve and provide that the commission shall consider the applicants' ranks when pre-approving applications. In the event the number of applicants exceeds statutory license limits and the applicants are equally ranked, a public lottery will determine the license recipient. The commission may rescind approval if the grower is not operational within one year of pre-approval. Following pre-approval, an applicant must submit an audited financial statement and a second application fee. The commission may then issue a license to grow medical cannabis following specified determinations. The regulations address transfers of ownership interests and changes of location of operation. The regulations establish procedures for the renewal of grower licenses, including the denial of renewal under certain circumstances. Finally, the regulations require each grower, on June 1 of each year, to report to the commission on the licensee's minority owners and employees.

Chapter 10.62.09 concerns medical cannabis grower agents. A grower agent must be at least 21 years of age and register with the commission, may not be registered if previously convicted of a felony drug offense, and may be disqualified by the commission from registration due to an absence of good moral character. The regulations govern grower agent identification cards, including card information, required display while at licensed grower premises, and procedures for replacement. The regulations establish procedures relating to the termination of a registered grower agent, require drug screening for prospective grower agents, and require certain training for registered grower agents. In addition, each registered grower agent must agree to adhere to the State alcohol and drug-free workplace policy. Finally, each licensed grower must verify to the commission every year, on a date determined by the commission, that no registered grower agent has been convicted of a felony drug offense.

Chapter 10.62.10 concerns medical cannabis grower premises. The licensed premises must be located within the State and conform to local zoning and planning requirements. The premises may not undergo a major renovation or modification without prior approval of the commission. The regulations specify security requirements related to the field cultivation of medical cannabis. The regulations also address requisite security hardware, security lighting, security alarm systems, video surveillance, and procedures for admission of visitors to nonpublic areas of the grower premises. A licensed grower must maintain a log of all visitors to nonpublic areas for two years.

Chapter 10.62.11 addresses medical cannabis growing controls. A licensed grower must adopt certain written standard operating procedures to promote good growing and handling practices. The regulations also govern horticultural controls, including: water quality; fertilizer; monitoring, recording, and regulating certain growing conditions; ventilation; pest control and monitoring; sanitation; and green waste. Finally, the regulations address the maintenance, cleaning, and calibration of growing equipment.

Chapter 10.62.12 concerns inventory control by a grower. The regulations require a licensed grower to: use a perpetual inventory control system to track the grower's medical cannabis stock; record information concerning raw material for cultivation; tag and enter each plant into inventory control as soon as practical; update inventory control for harvested medical cannabis; audit discrepancies between inventory of stock and inventory control within one business day of discovery; report instances of theft or diversion within one day of discovery; and accept the return of any medical cannabis from specified parties for destruction. The regulations prohibit a licensed grower or registered grower agent from distributing any medical

cannabis to any person if the grower or grower agent knows, or should have reason to know, that the distribution or the medical marijuana does not comply with statutory requirements.

Chapter 10.62.13 concerns medical cannabis shipment packaging and requires a licensee to repackage the shipment into a container constructed of tamper-evident opaque material and sealed with tamper-evident tape. Each package in a shipment of products containing cannabis must include a certain label that is conspicuously placed on the package.

Chapter 10.62.14 provides that a licensee may dispense medical cannabis at a facility for which the licensee has obtained a license to dispense medical cannabis. The regulations provide that the facility must be constructed and operated in accordance with certain regulations related to medical cannabis dispensary premises.

Chapter 10.62.15 addresses medical cannabis grower quality control. The regulations address production and process controls, inspections by growers during cultivation, holding procedures, testing by specified independent laboratories, certificates of analysis, the determination to release a batch of medical cannabis, stability testing and retention sampling, and quarterly reports to the commission of products and their specifications.

Chapter 10.62.16 sets forth the requirements for independent testing laboratory registration and the standards of care to be followed by the laboratories. An independent testing laboratory registration is valid for two years and may be renewed by providing certain information to the commission. No independent testing laboratory may handle, test, or analyze cannabis unless the laboratory: (1) has been registered by the commission; (2) is independent from all other persons and entities involved in the medical cannabis industry; (3) is accredited by an accreditation body or has a provisional registration from the commission; and (4) has established standard operating procedures that provide for adequate chain of custody controls for samples transferred to the laboratory for testing.

Chapter 10.62.17 concerns complaints, adverse events, and recall. The regulations require a licensed grower, licensed processor, licensed dispensary, certifying physician, and the commission to establish a procedure to receive, organize, store, and respond to any complaint regarding medical cannabis and adverse events. In addition, the regulations address: the reporting of serious adverse events to the commission and specified parties; investigations by growers or dispensaries; the recall of products under specified circumstances; and the custody of recalled products.

Chapter 10.62.18 concerns shipment of products between licensees. The regulations: require the installation of a specified electronic manifest system to record chain of custody; require the preparation of a specified electronic manifest for each shipment; establish requirements for transportation agents; provide procedures for the transportation of products containing medical cannabis; and establish requirements for medical cannabis transport vehicles.

Chapter 10.62.19 establishes the requirements for obtaining a medical cannabis processor license, including the documents to be included when applying for a license. An applicant for a processor license must provide criminal history record information to the commission for processor agents and individual investors with 5% or more of investment. An individual required to provide personal and background information must provide a statement that irrevocably gives consent to the commission and persons authorized by the commission to verify all information provided in the application documents and conduct a background investigation of

the individual. The regulations also provide for the review of the application by the commission and require the commission to rank the applications based on certain weighted criteria. The commission shall pre-approve a number of licenses sufficient to supply the demand for medical cannabis concentrates and medical cannabis-infused products in a range or routes of administration desired by qualifying patients. If there are more qualified applications than the number of licenses available and there is a numerical tie for the last license, the last pre-approved license shall be determined by public lottery. The commission may rescind pre-approval of a processor license if the processor is not operational with one year of pre-approval. Following pre-approval, an applicant must submit an audited financial statement and a second application fee. The commission may then issue a license to be a licensed processor following specified determinations. The regulations address transfers of ownership interests and changes of location of operation. The regulations establish procedures for the renewal of processor licenses, including the denial of renewal under certain circumstances.

Chapter 10.62.20 concerns medical cannabis processor agents. A processor agent must be at least 21 years of age and register with the commission, may not be registered if previously convicted of a felony drug offense, and may be disqualified by the commission from registration due to an absence of good moral character. The regulations govern registered processor agent identification cards, including card information, required display while at a licensed processor's premises, and procedures for replacement. The regulations establish procedures relating to the termination of a registered processor agent, require drug screening for prospective processor agents, and require certain training for registered processor agents. In addition, each registered processor agent must agree to adhere to the State alcohol and drug-free workplace policy. Finally, each licensed processor must verify to the commission every year, on a date determined by the commission, that no registered processor agent has been convicted of a felony drug offense.

Chapter 10.62.21 addresses the medical cannabis processor premises. The licensed premises must be located within the State and conform to local zoning and planning requirements. The premises may not undergo a major renovation or modification without prior approval of the commission. The regulations require the premises of a licensee to be constructed to prevent unauthorized entry. The regulations also address requisite security lighting, security alarm systems, video surveillance, and procedures for admission of visitors to nonpublic areas of the processor's premises. A licensed processor must maintain a log of all visitors to nonpublic areas for two years.

Chapter 10.62.22 governs medical cannabis processor operations. A medical cannabis processor must establish standard operating procedures, create and use a certain perpetual inventory control system, and train each registered processor agent in the standard operating procedures. The regulations establish the procedures to be followed by a medical cannabis processor when receiving products containing medical cannabis, and require a processor to maintain certain standard operating procedures related to the sanitary storage of medical cannabis and equipment sanitation. A processor must submit to the commission at the end of the month following each calendar quarter a list of the products and the products' specifications that the licensee offered for distribution in the previous calendar quarter.

Chapter 10.62.23 concerns medical cannabis concentrates and medical cannabis-infused products and requires a licensed processor to follow specified procedures. The regulations require a licensee to use an independent testing laboratory that is required to issue a certificate of analysis for each lot to report certain information regarding the safety of the lot. Processes to be

followed by a licensed processor on the determination that a batch may be released, as well as the requirements for stability testing and retention sampling, are also set forth in the regulations. Finally, the regulations require a licensee to submit to the commission within 30 days following the end of a quarter a list of the products and the products' specifications that the licensee offered for distribution in the quarter.

Chapter 10.62.24 concerns packaging of medical cannabis finished products. The regulations require all items to be individually packaged at the original point of processing and outlines the packaging requirements. The regulations prohibit certain packaging, including packaging that resembles any commercially available candy, snack, baked good, or beverage; or a cartoon, color scheme, image, graphic, or feature that might make the package attractive to children.

Chapter 10.62.25 sets forth the requirements to obtain a medical cannabis dispensary license, including the documents to be included when applying for a license. An applicant for a dispensary license must submit to the commission an application for a license for each senatorial district in which it is competing for a license. An applicant for a dispensary license must provide criminal history record information to the commission for dispensary agents and individual investors with 5% or more of investment. An individual required to provide personal and background information must provide a statement that irrevocably gives consent to the commission and persons authorized by the commission to verify all information provided in the application documents and conduct a background investigation of the individual. The regulations also provide for the review of the application by the commission and require the commission to rank the applications based on certain weighted criteria. The commission may issue pre-approvals of up to two licensed dispensaries per senatorial district, other than the number of licensed grower dispensary facilities located in the senatorial district. The commission may rescind pre-approval of a dispensary license if the dispensary is not operational with one year of pre-approval. Following pre-approval, an applicant must submit an audited financial statement and a second application fee. The commission may then issue a license to be a licensed dispensary following specified determinations. The regulations address transfers of ownership interests and changes of location of operation. The regulations establish procedures for the renewal of dispensary licenses, including the denial of renewal under certain circumstances.

Chapter 10.62.26 establishes the requirements to be a registered dispensary agent. A dispensary agent must be at least 21 years of age and register with the commission, may not be registered if previously convicted of a felony drug offense, and may be disqualified by the commission from registration due to an absence of good moral character. The regulations govern registered dispensary agent identification cards, including card information, required display while at a licensed dispensary's premises, and procedures for replacement. The regulations establish procedures relating to the termination of a registered dispensary agent, require drug screening for prospective dispensary agents, and require certain training for registered dispensary agents. In addition, each registered dispensary agent must agree to adhere to the State alcohol and drug-free workplace policy. Finally, each licensed dispensary must verify to the commission every year, on a date determined by the commission, that no registered dispensary agent has been convicted of a felony drug offense.

Chapter 10.62.27 concerns licensed dispensary premises. The licensed premises must be: located within the State, separate from the premises of a licensed processor, and conform to local zoning and planning requirements. The premises may not undergo a major renovation or

modification without prior approval of the commission. The regulations require the premises of a licensee to be constructed to prevent unauthorized entry. A licensed dispensary must contain a certain secure room to store the medical cannabis inventory. The regulations also address requisite security lighting, security alarm systems, video surveillance, and procedures for admission of visitors to nonpublic areas of the processor's premises. A licensed dispensary must maintain a log of all visitors to nonpublic areas for two years. A licensee must divide the licensed dispensary premises between a public zone and an operations zone.

Chapter 10.62.28 concerns licensed dispensary operations. A medical cannabis dispensary must establish standard operating procedures, create and use a certain perpetual inventory control system, and train each registered dispensary agent in the standard operating procedures. The regulations establish the procedures to be followed by a medical cannabis dispensary when receiving products containing medical cannabis. A licensee must maintain the cleanliness of any building or equipment used to store or display medical cannabis, and a registered dispensary agent is required to comply with certain standard operating procedures to maintain the medical cannabis free from contamination. The regulations also address equipment sanitation, the routine calibration of certain equipment, and maintenance logs related to the cleaning, maintenance, and calibration of equipment.

Chapter 10.62.29 addresses licensed dispensary packaging and labeling for distribution. The regulations set forth the packaging requirements for medical cannabis that is to be distributed to a qualifying patient or caregiver. At a licensed dispensary, medical cannabis may only be prepared or repackaged in area of the operations zone designed for that purpose. The regulations also specify the labeling requirements for a package of medical cannabis for a qualifying patient.

Chapter 10.62.30 concerns the dispensing of medical cannabis. A dispensary must notify the commission that a qualifying patient or caregiver has presented a written certification. In the service area of a dispensary, a registered dispensary agent must escort a member of the public and maintain visual contact at all times. The regulations prohibit the consumption of medical cannabis at the licensed premises and set forth the procedure for dispensing medical cannabis, which may only be dispensed to a qualifying patient or caregiver who has presented a government-issued identification card. Before dispensing medical cannabis, a dispensary agent is required to query the commission's data network and make a certain verification. In addition, the regulations set forth the process for the delivery of medical cannabis from the dispensary to the qualifying patient or caregiver. Before medical cannabis is dispensed, the qualifying patient or caregiver is required to make a certain attestation. The regulations also address dispensing controls, the transfer of medical cannabis, and the disposal of green waste. Finally, the regulations require a dispensary to submit to the commission on the last day of the month following each quarter a list of the products that the licensee offered for distribution in the quarter.

Chapter 10.62.31 authorizes a licensed dispensary to appoint an individual who is a Maryland-licensed physician, nurse practitioner, or pharmacist to function as clinical director.

Chapter 10.62.32 addresses the maintenance of records by licensed growers, processors, and dispensaries and requires the licensees to maintain a searchable, secure, tamper-evident record of each distribution that contains certain information. In addition, licensees and certifying physicians must maintain a record for a period of five years.

Chapter 10.62.33 concerns inspections and provides that submission of an application to be a licensed grower, licensed processor, licensed dispensary, or independent testing laboratory irrevocably grants the commission consent to conduct all inspections necessary to ensure compliance with State law and regulations. The regulations authorize the commission to conduct announced and unannounced inspections of the facilities of licensed growers, licensed processors, licensed dispensaries, and independent testing laboratories subject to the commission's regulation, mission, and function, to determine compliance with statute and regulations. During an inspection, the commission may obtain samples of certain laboratory products for testing, and if the inspector questions the quality of any medical cannabis, the inspector may contract with an independent testing laboratory to analyze the samples. The regulations authorize an inspector to suspend the distribution of some or all medical cannabis, order immediate evacuation of the premises, or quarantine some or all medical cannabis under certain circumstances. Following a review of the inspection findings, the commission may take additional specified actions. An inspector is required to prepare a report of each inspection and share the report with the inspected entity. Within 10 business days from the date of delivery of the report, the entity must respond in writing to any suggestion or demand for corrective action and provide a plan and timetable for corrective action. If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, or the risk to public health, an inspector may direct that the licensed premises may not distribute or participate in the distribution of any medical cannabis until the violation has been corrected and the premises pass reinspection.

Chapter 10.62.34 addresses discipline and enforcement. If the commission finds there is a reasonable likelihood of diversion, contamination of medical cannabis, or any risk to the health of a patient or other individual, after written notice and a specified hearing, the commission may: (1) impose a fine of up to $10,000 per violation on a licensed grower, licensed processor, licensed dispensary, or registered independent testing laboratory; (2) deny the license or registration; (3) suspend the license, licensee, agent, employee, registration, or registrant; or (4) revoke the license or registration. The regulations also set forth the disciplinary and enforcement actions that the commission may take in the event the commission finds a pattern of deviation from standard operating procedure or the terms set forth in the application or the license. In the event the commission finds that a licensee, registrant, agent, or employee violates the regulations, after written notice and a specified hearing, the commission may: (1) impose a fine of up to $5,000 per violation on a licensed grower, licensed processor, licensed dispensary, or registered independent testing laboratory; (2) suspend the licensee, agent, employee, registration, or registrant; or (3) revoke the license or registration. Finally, the regulations authorize the commission to deny a certifying physician's application for registration, or revoke a registration to certify a physician under certain circumstances.

Chapter 10.62.35 establishes the following fees:

Grower-only fees	Application fee	$6,000 (Stage 1 - $2,000; Stage 2 - $4,000)
	Annual license fee	$125,000
Grower-dispensary fees	Application fee	$11,000 (Stage 1 - $3,000; Stage 2 - $8,000)
	Annual license fee	$165,000
Grower agent fees	Registration fee	$200
	Replacement identification card fee	$100

Processor fees	Application fee	$6,000 (Stage 1 - $2,000; Stage 2 - $4,000)
	Annual license fee	$40,000
Processor agent fees	Registration fee Replacement identification card fee	$200 $100
Dispensary fees	Application fee	$5,000 (Stage 1 - $1.000; Stage 2 - $4,000)
	Annual license fee	$40,000
Dispensary agent fees	Registration fee	$200
	Replacement registration card fee	$100
Qualifying patient and caregiver fees	Identification card base fee	$50
	Replacement identification card fee	$100
Independent testing laboratory fees	Registration fee	$100
	Renewal fee	$100
Independent testing laboratory employee fees	Registration fee	$200
	Renewal fee	$100
Miscellaneous fees	Transfer of ownership of grower license, processor, or dispensary license	$7,000
	Change in location of premises of licensed entity	$7,000
	License reinstatement fee	$2,000

Legal Issue

The regulations present no legal issue of concern.

The commission has the legal authority to set reasonable fees to cover its costs. Although there are no legal issues associated with the regulations, there is inconsistency in the administration of fees. The regulations include in the fee schedule a $200 fee for grower agent, dispensary agent, and processor agent registration cards and a $100 fee for the replacement of these cards. The agents listed above are each required by statute (and these regulations) to obtain a registration card from the commission, but the process does not include payment of a fee for registration. If a replacement card is needed, the process does incorporate payment of the $100 replacement card fee. Thus, the fiscal analysis assumes only minimal revenue from replacement card fees and no revenue from issuance of registration cards for these agents. For consistency with statute and within the regulations, the commission may wish to remove the $200 fee for issuance of agent registration cards (but retain the replacement card fee for those agents).

Moreover, the regulations also include in the fee schedule a $200 fee for the registration of independent testing laboratory employees and a $100 replacement identification card fee. Unlike grower agents, dispensary agents, and processor agents, there is no statutory (or regulatory) requirement for the registration of independent laboratory employees. Due to the lack of a requirement to issue a registration card to independent laboratory employees, the fiscal

analysis assumes no revenue from the independent laboratory employees. The commission may wish to remove independent laboratory employees from the fee schedule for consistency with statute.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites §§ 13-3301 through 13-3316 of the Health – General Article as authority for the regulations. Section 13-3302 requires the department to adopt regulations that establish the requirements for identification cards provided by the commission. Section 13-3303(g) authorizes the commission to set reasonable fees to cover the costs of operating the commission. Section 13-3306 authorizes the commission to license medical cannabis growers that meet all requirements established by the commission. Section 13-3307 requires the commission to establish requirements for security and product handling procedures that a dispensary must meet to obtain a license, including a requirement for a product-tracking system. Section 13-3307 also authorizes the commission to inspect a dispensary to ensure compliance with the subtitle. Section 13-3309 requires a processor to be licensed by the commission, requires the commission to establish a certain application review process and security and product handling procedures, and authorizes the commission to inspect the processor. Section 13-3311 requires the commission to adopt regulations that establish the standards and requirements to be met by an independent testing laboratory to obtain a registration, the standards of care to be followed by an independent testing laboratory, the initial and renewal terms for an independent laboratory registration, and the bases and processes for denial, revocation, and suspension of a registration of an independent testing laboratory. Section 13-3311 also authorizes the commission to inspect independent testing laboratories. Section 13-3316 provides that, on or before September 15, 2014, the commission shall adopt regulations to implement the provisions of Title 13, Subtitle 33 of the Health – General Article.

This authority is correct and complete. The regulations comply with the legislative intent of the law.

Fiscal Analysis

The regulations have no material fiscal impact on State or local government expenditures beyond the expenditures assumed for the same period in the fiscal and policy notes for Chapters 240 and 256 of 2014 and Chapter 251 of 2015. This estimate accounts for delayed start-up costs from fiscal 2015 to fiscal 2016. While special fund fee revenues were anticipated as early as fiscal 2016, the amount could not previously be estimated. However, under these regulations and with aggressive implementation and the assumptions outlined below, as much as $4.5 million in special fund fee revenues *could* be realized in fiscal 2016 (with approximately $4.2 million in fiscal 2017 and $4.4 million in 2018); some portion of this revenue estimate could also be delayed. General fund revenues may increase minimally due to imposition of fines.

Agency Estimate of Projected Fiscal Impact

Expenditures

Although the regulations submitted by the department indicate that expenditures increase by $2.5 million to $3.0 million annually, the commission now advises that special fund expenditures related to running the Natalie M. LaPrade Medical Cannabis Commission and implementing Maryland's medical cannabis program increase by approximately $1.8 million beginning in fiscal 2016 and about $1.5 million annually thereafter. The Department of Legislative Services concurs with the total expenditures now estimated by the commission. However, the Department of Legislative Services notes that the commission likely requires supplemental general funds to cover expenditures (see budget discussion below).

Moreover, the Department of Legislative Services advises that the regulations primarily implement Chapters 240 and 256 of 2014 and Chapter 251 of 2015 (they also implement Chapter 403 of 2013, which established the commission). Thus, the $1.8 million in expenditures for fiscal 2016 has already been accounted for in the fiscal and policy notes for that legislation. However, the fiscal and policy notes assumed that most of the start-up costs would have to be incurred in fiscal 2015, not fiscal 2016 as the commission now estimates. Even so, this assumption was primarily due to the aggressive timeframe for certain activities specified in the legislation. The shift in timing accounts for the bulk of the higher costs in fiscal 2016. Nevertheless, the commission also has higher estimates for certain items – mainly related to the website, identification cards, and inspections. Although the commission's estimates are higher and there are some differences, the estimated expenditures are largely consistent with those in the fiscal and policy notes. Further, the fiscal and policy notes reflected the *minimum* costs necessary to implement the program and advised that costs could be higher.

Revenues

The department did not include a revenue estimate with its submission of the regulations; however, discussions with the commission revealed that, under best-case scenarios, special fund fee revenues could increase by about $4.5 million in fiscal 2016, by $4.2 million in fiscal 2017, and by approximately $4.4 million in fiscal 2018 and annually thereafter due to the regulations. In large part, the relatively stable fee revenue is due to licensees being charged *annual* license fees under the regulations regardless of the licensure term for either initial (four-year) or renewal (two-year) licenses. All revenue is considered to be newly recognized since the fiscal and policy notes did not quantify a special fund revenue estimate because fee levels were not set in statute and the level of interest in participation was not clear. The fiscal and policy notes did advise, however, that the commission is simply authorized to set *reasonable* fees to cover its operating costs.

The Department of Legislative Services also notes that general fund revenues could increase minimally due to imposition of fines under the regulations.

***Fee Revenues from Grower Licenses, Dispensary Licenses, Processor Licenses, and Independent Testing Laboratory* Registrations:** The regulations allow for approval of up to 15 grower licenses through May 2018. This is consistent with the statutory limit in place until June 2018, and the commission assumes that 15 will be approved in fiscal 2016. The commission also estimates that as many as 50 applicants will submit an application at Stage 1

and pay that fee but that only 15 will proceed through the entire process. Potential growers must pay an application fee set at $6,000 (payable in two unequal installments as the applicant progresses through the approval process) and an annual licensing fee of $125,000 upon approval. Though allowed, the commission does not anticipate an increase in the number of licensed growers, at least in the first few years of implementation. Thus, revenues attributable to grower license fees total just over $2.0 million in fiscal 2016 (50 applicants paying $2,000 on submission at Stage 1, 15 paying the $4,000 balance of the application fee at Stage 2, and 15 paying the first-year license fee of $125,000 when approved) and about $1.9 million annually thereafter (15 paying the annual licensing fee of $125,000).

The regulations allow for approval of up to 94 dispensary licenses (two per senatorial district). This restriction is established in the proposed regulations; no such statutory limit exists. Even so, the commission assumes just 45 licenses will be approved in fiscal 2016, with as many as 100 applicants submitting an application at Stage 1. Potential dispensaries must pay an application fee of $5,000 (payable in two unequal installments as the applicant progresses through the approval process) and an annual licensing fee of $40,000 upon approval. The commission assumes no increase in the number of licenses issued in the first few years. Thus, revenues attributable to dispensary license fees total just over $2.0 million in fiscal 2016 (100 applicants paying $1,000 on submission at Stage 1, 45 paying the $4,000 balance of the application fee at Stage 2, and 45 paying the first-year installment of $40,000 when approved) and approximately $1.8 million annually thereafter (45 paying the annual licensing fee of $40,000 or the same amount each year for renewal).

The regulations establish grower-dispensary licenses, with the applicable fee structure simply being a combination of the grower and dispensary fees outlined above. The commission did not provide separate revenue estimates for this category of license. Thus, this analysis assumes that the regulations still restrict the total number of growers and dispensaries to 15 (through fiscal 2018) and 94, respectively, even if some are technically combined grower-dispensaries.

The regulations establish processor licenses and allow for the commission to pre-approve a number of licenses *sufficient to supply the demand*. There is no concrete limit, as consistent with statute. Potential processors must pay an application fee set at $6,000 (payable in two unequal installments as the applicant progresses through the approval process) and an annual licensing fee of $40,000 upon approval. The commission estimates that five processors will apply and gain approval beginning in fiscal 2016. The commission assumes no increase in the number of processors in the first few years. Thus, revenues attributable to processor license fees total approximately $230,000 in fiscal 2016 (five applicants paying $2,000 at Stage 1, five paying the $4,000 balance of the application fee at Stage 2, and five paying the first-year license fee of $40,000 when approved) and by $200,000 annually thereafter (five paying the annual licensing fee of $40,000).

The regulations also establish $100 registration and renewal fees for independent testing laboratories. Registrations are valid for two years. The regulations do not limit the number of registered independent testing laboratories, but statute requires the commission to register at least one independent testing laboratory. The commission estimates that five independent testing laboratories will register in fiscal 2016. Thus, revenues attributable to independent testing laboratory registration fees total approximately $500 in fiscal 2016 and $500 in each renewal year thereafter.

***Fee Revenues from Qualifying Patient and Caregiver Identification Card*:** *The* regulations specify that the fee for a qualifying patient or caregiver identification card is $50. An identification card is valid for two years and must be renewed before it expires. The registration process established in the regulations *authorizes* a qualifying patient but *requires* his or her caregiver(s) to apply to the commission for an identification card and submit the required fee. If a replacement identification card has to be issued, the patient or caregiver must pay a $100 fee. (Obtaining an identification card appears to be optional for a qualifying patient as the regulations specify that a qualifying patient *may* apply for a card and further specify that a qualifying patient in hospice care is *exempt* from doing so. However, obtaining a card is a requirement for a caregiver as the regulations specify that a caregiver *shall* apply to the commission for a card upon being designated.) The commission estimates that only 20% of all participating individuals (qualifying patients and caregivers combined) will apply for an identification card annually and that 0.75% of Maryland's population, or 45,651 individuals (again, qualifying patients and caregivers combined), will participate in the medical cannabis program by its third year of implementation (fiscal 2018), with approximately 11,322 participating in the first year (presumed to be fiscal 2016). This estimate is based on Maryland's population in comparison to other states with medical cannabis programs. Thus, the commission estimates that revenues from identification cards for qualifying patients and their caregivers total approximately $113,200 in fiscal 2016 (2,264 individuals paying the $50 fee), $341,000 in fiscal 2017 (6,820 individuals paying the $50 fee), and $456,500 in fiscal 2018 (9,130 individuals paying the $50 fee).

***Minimal Revenue Associated with Replacement Cards for Grower Agents, Dispensary Agents, and Processor Agents*:** *The* regulations establish fees of $200 for grower agent, dispensary agent, and processor agent registration cards. However, the Department of Legislative Services advises that, and the commission concurs, although the regulations set the *amount* of the fees in the fee schedule, there is no regulatory requirement for *payment* of a registration fee as part of the agent registration process. Likewise, there is no statutory requirement for *payment* of a registration fee. Consistent with statute, the regulations clearly require the licensee (either the grower, dispensary, or processor, as appropriate) to apply to the commission for a registration card for each of its agents; the commission has to issue the registration cards. (It is assumed that the license fee paid by a grower, dispensary, or processor encompasses issuance of the registration cards.) The regulations do include a requirement for a licensee or registrant to apply for and *pay* for a replacement card should the original be lost or stolen (at a cost of $100). Thus, this analysis reflects only minimal revenue from the replacement card fees.

***No Revenue Associated with Registering Independent Testing Laboratory Employees*:** Similarly, the regulations establish a $200 registration and $100 replacement identification card fee for independent testing laboratory employees. However, the Department of Legislative Services advises that, and the commission concurs, although the regulations set the *amount* of the fees in the fee schedule, there is no regulatory requirement for registration of independent testing laboratory *employees* and no requirement to obtain registration cards. Likewise, there is no statutory requirement for registration of such employees. An independent testing laboratory is merely required to submit certain pieces of information for current employees under the regulations. Thus, this analysis reflects no revenue from registration of independent testing laboratory employees.

***No Revenue Associated with Approval of Certifying Physicians*:** The Department of Legislative Services notes that there is no fee associated with approving certifying physicians, consistent with statute; thus, no revenue is anticipated for this process.

***Imposition of Fines*:** The regulations authorize the commission to impose a fine of up to $10,000 per violation if the commission finds a reasonable likelihood of diversion, contamination of medical cannabis, or any risk to the health of a patient or any other individual. The commission is also authorized to impose a fine of up to $5,000 per violation if it finds a pattern of deviations from standard operating procedures (but that pattern does not directly create a risk of endangering the health or safety of a patient). Likewise, the commission may impose a fine of up to $5,000 per violation for any violation of the regulations. Fines may be imposed against licensed growers, licensed processors, licensed dispensaries, or independent testing laboratories after written notice and a hearing. Although not specified in the regulations, any such fines imposed would accrue to the general fund. Thus, general fund revenues could increase minimally.

***Conclusion*:** The commission estimates special fund fee revenue of almost $4.5 million in fiscal 2016, $4.2 million in fiscal 2017, and $4.4 million in 2018. This estimate assumes that, in fiscal 2016, 50 growers and 100 dispensaries apply for licensure and pay the Stage 1 application fees but only 15 and 45, respectively, complete the process of becoming licensed. The estimate also assumes that 5 processors pay the entire application and annual licensing fees and that 5 independent testing laboratories pay the $100 registration fee. The estimate also includes fee revenue from issuance of qualifying patient and caregiver identification cards. Under this scenario, the commission would be able to cover all its costs with special funds in fiscal 2016 (with revenues not likely realized until the fourth quarter) and still have a healthy fund balance. The Department of Legislative Services concurs but notes that these revenue estimates are high-end estimates based on relatively strong participation within the next year, and it is likely that the commission will not realize fee revenues of this magnitude. It is unclear when this program can be operational to the point where growers, dispensaries, and processors will pay license fees and patients will be able to purchase medical cannabis. The fiscal and policy notes estimated that the program *could* be operational by 2016 under an aggressive timeframe. However, given the high fee levels and stringent facility requirements incorporated into the regulations, businesses may need additional time to meet the requirements, obtain funding, and begin production.

The Department of Legislative Services also notes that general fund revenues could increase minimally due to imposition of fines.

Impact on Budget

The Governor's proposed fiscal 2016 budget fully funded the commission with $1.0 million in general funds and more than $800,000 in special funds. However, as passed, the fiscal 2016 budget eliminated the $1.0 million in general fund spending for the commission and authorized the commission to process a budget amendment to provide for these costs with special funds. Further, if insufficient special fund revenue is collected in fiscal 2016 to do so, the commission is directed to seek a general fund deficiency appropriation with its fiscal 2017 budget submission for approval at the 2016 legislative session. The Department of Legislative Services notes, as addressed in the fiscal and policy note for Chapter 251 of 2015, that it is likely that some portion of general funding for the commission will have to be maintained in fiscal

2016 and even in future years because cost-recovery is not required. Moreover, fees set at a level to cover costs would likely not meet the *reasonableness* standard.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have a meaningful economic impact on small businesses in Maryland and that the regulations provide a positive impact on small businesses through the creation of jobs in the industry. The department states that costs for small businesses include licensing, security, construction, and other start-up costs. Businesses in the medical cannabis program are assumed to be predominantly small businesses.

The Department of Legislative Services concurs that the regulations have a meaningful economic impact on small businesses in Maryland, but not that the entire impact is positive. The application and licensing fees are set at significantly higher levels than the *reasonable* fee levels anticipated in the fiscal and policy notes. The commission is charged with actively seeking to achieve racial, ethnic, and geographic diversity as well as encouraging minority business enterprises to apply for medical cannabis operations. The Department of Legislative Services advises that the costs associated with licensure are so high, particularly for growers, that the regulations may limit the commission's ability to attract the participation of diverse small businesses as directed by statute and established in the regulations.

The Department of Legislative Services does note that the regulations likely have a significant positive impact on independent testing laboratories. The testing requirements for growers, dispensaries, and processors alike are considerable and well beyond those imagined in the fiscal and policy notes. Thus, independent testing laboratories benefit significantly to the extent that they are small businesses.

Additional Comments

Medical cannabis is a multibillion dollar industry in the United States, and more than 20 states have active medical cannabis programs. Many states that implement medical cannabis programs establish regulated dispensaries, like Maryland. According to the Marijuana Policy Project, dispensary application fees generally range between $1,000 and $5,000 and are often refundable for those applications that fail. Annual licensing or registration fees range from $5,000 to $20,000. However, the Illinois Compassionate Use of Medical Marijuana Pilot Program Act, enacted January 1, 2014, sets fees significantly higher than the more typical national range. Individuals wishing to obtain a cultivation center permit in Illinois must pay a $25,000 application fee and an additional $200,000 for each permit that is granted. Renewals of a cultivation center permit are $100,000. Application fees for potential dispensaries are $5,000, with a registration fee of $30,000 and an annual renewal fee of $25,000.

The fee levels for potential growers, dispensaries, and processors in Maryland are significantly higher than comparable fees in almost every other state with medical cannabis programs. The fee levels for the Maryland medical cannabis program as well as the costs of compliance with the security, testing, and other requirements established by the regulations may mean that high product costs are passed on to qualifying patients.

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